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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,351	04/06/2005	Bart Gerard Boucherie	BOUC3022/JJC/PMB	7774

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BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER	
HUSON, MONICA ANNE	
ART UNIT	PAPER NUMBER
1791	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,351	BOUCHERIE, BART GERARD	
	Examiner	Art Unit	
	Monica A. Huson	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-30* is/are pending in the application.

4a) Of the above claim(s) *17-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *081707*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Art Unit: 1791

DETAILED ACTION

This office action is in response to the paper filed 20 November 2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiba (WO 01/70311), using a translation of the related document JP 2001-259031. Regarding Claim 1, Chiba shows that it is known to carry out a method of manufacturing plungers for medical syringes (para. 0001), said plunger comprising at least two parts including a longitudinal plunger body (Figure 1, element 5) made of plastic and a piston body provided at the front end of the plunger body (Figure 1, element 6), which piston body comprises a plastic which is softer than the plastic of the plunger body (para. 0011-0013), wherein said plunger or at least part of the plunger is formed by first manufacturing the piston and then the plunger body by means of injection molding, and wherein the plunger body is injected against the piston body, the piston having a front side and a side wall and being formed free of any flash lines (Figure 1; para. 0016-0018).

Regarding Claim 3, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the piston body and the plunger body are connected solely by adhesion between the plastics out of which they are made, without any meshing parts (Figure 1, para 0018).

Regarding Claim 4, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein at least one inwardly directed part is formed on the piston body and use is made during injection molding of a mold part having a protruding part in which one or several lateral recesses are provided, such that the mold part may be removed from the piston body due to the elastic flexibility of the piston body (Figure 5; para. 0002-0004; it is interpreted that the mold part will be the negative image of the molded body- when the piston has a inwardly directed part, the mold part will have a protrusion to form the inwardly directed part).

Regarding Claim 5, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the plastic forming the piston body is provided in a respective mold cavity via the back side of the piston body to be formed (Figure 2(c)).

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Jentzen (U.S. Patent 5,782,803). Jentzen shows that it is known to carry out a method for manufacturing plungers for medical syringes having at least a piston body comprising forming a part of the piston body at the location of the piston body which protrudes frontally from a front side of the piston body and which, when the plunger is located in a syringe, can penetrate at least partially through an outlet of the syringe (Figures 4-6; Column 3, lines 41-50), wherein the piston body part is formed of a material which is different from the material of the piston body, and herein the materials for forming the piston body and the protruding portion are formed with known processes (e.g. injection) such that the piston body can be made in one piece with a plunger body belonging to the plunger (Figure 7, element 300, 202).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Sorensen (U.S. Patent 5,030,406).

Regarding Claim 6, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show multicavity molding. Soresnsen shows that it is known to carry out a multicavity molding process wherein one article is formed in a first mold after which the article, while it is still held in a first part, is presented to a second mold cavity in which a second element of the article is then injected against the first article by means of injection molding, and wherein the mold cavities are of the desired final article shape, and the two plastics are connected to each other due to adhesion between the plastics (Figures 1-8). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Sorensen's multistep/multicavity molding process during Chiba's molding method in order to most efficiently form two parts of an article at the same time.

Regarding Claim 7, Chiba shows the process as claimed as discussed in the rejection of Claim 6 above, but he does not show simultaneously forming a second portion of the article at the same time as a first portion. Sorensen shows that it is known to carry out a method wherein the second body is formed such that it connects to first body, a subsequent first body is simultaneously being formed by means of a connector nozzle with which the first body is formed but in another mold cavity (Figures 1-8). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Sorensen's multistep/multicavity molding process during Chiba's molding method in order to most efficiently form two parts of an article at the same time.

Claim 8 is rejected under 35 USC 103(a) as being unpatentable over Chiba. Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the plunger body is formed in a mold, after which a mold part with the plunger body in it is presented against other mold parts in which the piston body is formed (Figures 2(a)-2(c); para. 0015). Although Chiba's process molds the plunger first and then the piston, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to mold the piston first followed by the plunger because selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. (*In re Burhaus*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946)).

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Schwartz (U.S. Patent 3,659,749).

Regarding Claim 9, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show an accessory at a front side of the piston body. Schwartz shows that it is known to carry out a method of manufacturing a piston and plunger including forming a plunger and an accessory located at a front side of the piston body, wherein the accessory is made of a different material than the piston (Figure 3, element 42). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's method in order to provide an intermixing syringe (see Schwartz, Column 2, lines 14-18).

Regarding Claim 10, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows using an accessory, wherein its material comprises glass (Column 3, lines 61-63; it is being interpreted that glass can be considered a plastic material of sorts since it can be melted and reshaped and molded again). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's harder material for the accessory during

Chiba's method in order to provide an intermixing syringe (see Schwartz, Column 2, lines 14-18).

Regarding Claim 11, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to carry out a plunger/piston manufacturing method including an accessory which comprises a part which extends frontally of a front side of the piston and which, when the plunger is situated in the syringe, can at least partially penetrate an outlet of the syringe (Figure 8, element 112, 117; Column 6, lines 3-44; it is noted that the remaining limitation of the claim is being considered solely as intended use). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Regarding Claim 12, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to make a plunger/piston assembly including an accessory comprising a part which enables creation of a passage between the front side and a rear side of the piston body when emptying the syringe (Column 6, lines 3-44; it is noted that the remaining limitation of the claim is being considered solely as intended use). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Regarding Claim 13, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to carry out a method of making a plunger/piston assembly including an accessory made as a separate part provided on a front side of the piston body (Figure 14). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Reynolds (U.S. Patent 4,861,335).

Regarding Claim 14, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show connecting the piston to the plunger at a later stage. Reynolds shows that it is known to carry out a method of forming a piston and a plunger, wherein the piston is attached to the plunger at a later stage after molding of the plunger and

part of the piston (Column 4, lines 56-68). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Reynolds' attachment process during Chiba's molding method in order to enable the attachment of various pistons to the end of the same plunger.

Regarding Claim 15, Reynolds shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show connecting the plunger to a drive element. Reynolds shows that it is known to carry out a method wherein the plunger cooperates with an associated drive element (Column 5, lines 57-68; Column 6, lines 1-3, 20-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Reynolds' drive element in combination with Chiba's plunger in order to accurately move and position the plunger during consumer use.

Response to Arguments

Applicant's arguments filed 20 November 2007 have been fully considered but they are not persuasive.

Applicant contends that Chiba does not show the instant invention because he does not show forming a piston first and then a plunger. This is not persuasive because, as noted in the office action, the examiner is interpreting element 5 as the piston body, and element 6 as the plunger. It is acknowledged that Chiba identifies elements 5 and 6 as a plunger and gasket, respectively, but the terminology does not impart an exclusive structure that cannot also be called by different terminology. Therefore, it is believed that interpreting element 5 as the piston and element 6 as the plunger is a reasonable interpretation. With this interpretation in mind, it is clear that Chiba shows molding the piston (element 5) prior to molding the plunger (element 6); see Figures 2(a)-2(c).

Applicant contends that all other claims are allowable because the other references used do not cure the alleged deficiency of Chiba noted above. This alleged deficiency is not persuasive as discussed above. Therefore, the rejections of the dependent claims are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone number is 571-272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Monica A Huson
Primary Examiner
Art Unit 1791

/Monica A Huson/
Primary Examiner, Art Unit 1791